

DAVID G. MANGUM (4085)
C. KEVIN SPEIRS (5350)
KRISTINE EDDE JOHNSON (7190)
MICHAEL R. MCCARTHY (8850)
PARSONS BEHLE & LATIMER
One Utah Center
201 South Main Street, Suite 1800
Salt Lake City, UT 841111
Telephone: (801) 532-1234
Facsimile: (801) 536-6111
ecf@parsonsbehle.com

BENJAMIN G. JACKSON (Cal Bar. No. 255358)
(*pro hac vice* motion to be filed)
MATTHEW GORDON (12526)
MYRIAD GENETICS, INC.
320 Wakara Way
Salt Lake City, UT 84108
Telephone: (801) 584-3600
Facsimile: (801) 584-3640
bjackson@myriad.com
mgordon@myriad.com

Attorneys for Plaintiffs

**IN THE UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF UTAH, CENTRAL DIVISION**

UNIVERSITY OF UTAH RESEARCH FOUNDATION, a division of the University of Utah, a Utah nonprofit corporation; TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, a Pennsylvania nonprofit corporation; HSC RESEARCH AND DEVELOPMENT LIMITED PARTNERSHIP, a Canadian limited partnership organized under the laws of the Province of Ontario; ENDORECHERCHE, INC., a Canadian corporation organized under the laws of the Province of Quebec, and MYRIAD GENETICS, INC., a Delaware corporation,

Plaintiffs,

DECLARATION OF ALEXANDER FORD

Case No. 2:13-cv-00640-RJS

Judge Robert J. Shelby

vs.

AMBRY GENETICS CORPORATION,
Defendant.

I, Alexander Ford, declare:

1. I am currently employed as the Chief Commercial Officer of Myriad Genetic Laboratories, Inc., a wholly-owned subsidiary of Myriad Genetics, Inc. Myriad Genetic Laboratories, Inc. conducts all of the clinical diagnostic testing on behalf of the Myriad affiliated group. I have held that position since January 15, 2013. Previously, beginning on July 1, 2011, I held the position of General Manager, Preventive Care Business Unit. Among other things, I have oversight responsibility for sales and marketing of Myriad's BRACAnalysis® genetic testing, which is used to confirm the presence and characterization of a mutation in the BRCA1 or BRCA2 gene. BRCA mutations are responsible for the majority of hereditary breast and ovarian cancers. The results of the BRACAnalysis® testing enable a patient and their medical provider to develop patient-specific medical management plans to significantly reduce the risk of developing those types of hereditary cancer. To date, Myriad's testing has benefited over one million patients.

2. BRACAnalysis® testing is very important to Myriad's business. As the first genetic test for a common, major disease (breast cancer), it has not only created and nurtured to maturity a new market for clinical diagnostic testing for hereditary cancer predisposition, but it also exhibits superior methodology and unparalleled reliability.

3. *BRACAnalysis®* testing has been on the market since 1996. Myriad has spent the entirety of this time improving the quality, accuracy and reliability of the test, which it has done in a number of ways.

4. Additionally, Myriad created and developed this market for hereditary breast/ovarian cancer predisposition testing from scratch through substantial capital investments in time and money in (a) conducting extensive clinical studies in support of medical industry guidelines regarding hereditary cancer predisposition testing; (b) developing a market of insurance reimbursement for such clinical diagnostic testing both with private payors and Medicare and Medicaid reimbursement; and (c) promoting physician and patient education surrounding the importance of hereditary cancer awareness and testing. Myriad has expended over \$500 million in developing its *BRACAnalysis®* testing and the market for molecular diagnostic testing. Much of this market development came only after years of work and many clinical trials and research studies to prove the importance of hereditary cancer testing, and the positive health-economic impact of testing.

5. Over the years, Myriad has developed and performs various operation procedures and quality checks, such as its proprietary DNA base calling software. These quality checks have resulted in a near-perfect accuracy rate.

6. The quality of *BRACAnalysis®* testing is also based on Myriad's extensive database of genetic variant information. This database was developed in part utilizing research and a \$100 million investment by Myriad, and also consists of data and research results derived from over 1,000,000 samples from patients and family members of patients who were identified as having "variants of unknown significance," meaning a genetic variation the effect of which (deleterious or otherwise) is unknown.

7. By building this database, Myriad has further improved its test quality by ensuring that its percentage of “variants of unknown significance” is less than 3%. This means that less than 3% of the patients that Myriad tests will receive a result indicating that he or she has a genetic variation, but the significance of the variant is unknown.

8. Until mid-June 2013, Myriad was the only company that commercially offered a full sequence test for the BRCA1 and BRCA2 genes in the United States. No other entity has been licensed the rights to conduct full BRCA1 and BRCA2 sequence testing.

9. On June 13, 2013, Ambry Genetics announced that it is now offering its own tests that include BRCA1 and BRCA2 testing. *See* <http://ambrygen.com/tests/brcaplus-%E2%80%93-high-risk-breast-cancer-panel> and <http://www.ambrygen.com/brca-beyond>.

10. Ambry also released a Cancer Test Requisition Form that offers various different tests, four of which (BreastNext, BRCAPlus, CancerNext and OvaNext) offer BRCA1 and/or BRCA2 panels. Attached hereto as Exh. 1.

11. Ambry further indicated that it will offer its BRCAPlus test for \$2,280, significantly below the price for Myriad’s integrated BRACAnalysis® test, which is priced at \$4,040.

12. The market for genetic testing is largely driven by third-party payors, such as insurers and/or HMOs. Nearly all of these payors cover BRACAnalysis testing, most with no out-of-pocket cost to the patient.

13. These are the entities that make the decisions regarding whether they will reimburse or pay for testing, not the physician or the patient.

14. Myriad's prices are set with the goal of allowing Myriad to capture the optimum pricing during the life of its patents, while providing the benefit of BRCA testing to a vast majority of insured individuals (with over 1,000,000 individuals tested).

15. However, Myriad's prices are constrained by the ability of employers to opt out of genetic testing in their insurance offerings if they determine that it has become too expensive. Pricing is also controlled by the ability of insurers to "not cover" or treat Myriad's testing as a "non-covered" benefit under its plans, forcing patients to pay the entire cost without insurance (or more limited insurance coverage).

16. Now that Ambry has entered the market, however, some third-party payors have already begun to exert pressure on Myriad to lower its prices in response to Ambry's discounted tests. In some instances, Myriad may be forced to do so in order to compete with Ambry.

17. These payors typically are not well-informed regarding the superior quality and reliability of Myriad's BRACAnalysis® test. For example, in contrast to Myriad's near-perfect error rate, Ambry's error rate may be as high as 4%. Attached hereto as Exh. 2.

18. In real-world numbers, at 96%, 1 in 25 patients tested with Ambry's tests will experience a false negative or a false positive. These patients potentially then could make decisions, such as whether to undergo surgery or other preventative measures, based upon this false information.

19. Also, Ambry's percentage of variance of unknown significance is between 25-30%, again in contrast to Myriad's which is less than 3%.

20. This percentage means that 70-75% of patients tested with Ambry's tests will be informed that they have a genetic variation, but that Ambry can offer no further information regarding that variation. This is significant because patients will most likely not be able to get a

second test as insurance generally does not reimburse for repetitive testing. Thus, the patient is informed that she has a genetic mutation, but will not know if it is deleterious or benign. Experience shows that patients will most likely engage in some prophylactic steps out of concern of having a mutation, and accordingly will incur unnecessary surgeries or other health care choices based on the assumption that the mutation is not benign.

21. In awareness of the pending expiration of some of its patents, Myriad has begun to formulate a marketing strategy to advise the public of the superiority of its tests. However, Myriad believed that it had the benefit of the remaining years of patent exclusivity to finalize and implement this strategy.

22. Therefore, Myriad has not had the time or opportunity to distinguish its tests and associated testing quality from competitors such as Ambry as it would if those competitors were barred from entry until the patents' expiration date.

23. Myriad also has a corporate strategy for its remaining years of patent exclusivity, including the development and introduction of products, such as Myriad's MyRisk™ hereditary cancer panel. This multi-gene panel, which will be introduced later this year, will offer testing of 25 different genes in six different cancers, including the BRCA genes.

I declare under penalty of perjury that the foregoing is true and correct.

DATED this 9th day of July, 2013.



ALEXANDER FORD

CERTIFICATE OF SERVICE

On this 9th day of July 2013, I hereby certify that I electronically filed the foregoing **DECLARATION OF ALEXANDER FORD** with the Clerk of Court using the CM/ECF system.

I also caused the foregoing to be served by hand, along with Plaintiffs Complaint and Motion for Preliminary Injunctive Relief and Memorandum in Support, on the following party:

Ambry Genetics Corporation
15 Argonaut
Aliso Viejo, CA 92656

/s/ David G. Mangum